



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0576; FRL-9907-46]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluoxastrobin in or on wheat, grain; and revises tolerances for milk; and milk, fat. Arysta LifeScience, North America, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0576, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0576 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0576, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2013 (78 FR 13296) (FRL-9380-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8130) by Arysta LifeScience, North America, LLC, 15401 Weston Pkwy., Suite 150, Cary, NC 27513. The petition requested that 40 CFR 180.609 be amended by establishing tolerances for residues of the fungicide, fluoxastrobin, (1*E*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, and its *Z*-isomer, (1*Z*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, in or on wheat, grain at 0.15 parts per million (ppm). The petition also requested that 40 CFR 180.609 be amended by revising tolerances for milk from 0.02 ppm to 0.03 ppm; and milk, fat from 0.50 ppm to 0.75 ppm. That document referenced a summary of the petition prepared by Arysta LifeScience, North America LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluoxastrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluoxastrobin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of

the sensitivities of major identifiable subgroups of consumers, including infants and children.

Following repeated exposure, fluoxastrobin has mild or low toxicity in all tested species except for the dog. Repeated oral administration to dogs resulted in adverse liver toxicity at considerably lower doses than those noted in other species. Based on species sensitivity, the effects observed in the dog were used as endpoints for risk assessment. In both the 90-day and one-year oral feeding studies in dogs, the liver appeared to be the target organ. In dogs, mice, and rats, the kidney was another target organ. There was no indication of an adverse effect attributable to a single dose. Based on developmental toxicity studies (rat and rabbit) and a two-generation reproduction study (rat), there was neither increased susceptibility of pre-/postnatal exposure to fluoxastrobin, nor adverse effects on reproduction. Furthermore, acute neurotoxic effects were not seen in an acute neurotoxicity study in rats up to the limit dose of 2,000 milligrams/kilogram/day (mg/kg/day). In a subchronic neurotoxicity study in rats, fluoxastrobin did not elicit any neurotoxic effects. Repeated dose studies of fluoxastrobin in the database did not show immunotoxic effects in rats. Results of genotoxicity testing were negative and there were no treatment-related carcinogenicity findings in adequately performed carcinogenicity studies in rats and mice. Therefore, fluoxastrobin is classified as “not likely to be carcinogenic to humans.” Specific information on the studies received and the nature of the adverse effects caused by fluoxastrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, “Fluoxastrobin. Aggregate Human Health Risk Assessment for the Proposed New Uses on Melon

Subgroup 9A and Sorghum, Along with Establishment of Permanent Tolerances on Wheat, and Amendments to Established Tolerances on Milk and Milk Fat” on pages 26-31 in docket ID number EPA-HQ-OPP-2012-0576.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fluoxastrobin used for human risk assessment is shown in Table 1 of this unit.

Table 1.-- Summary of Toxicological Doses and Endpoints for Fluoxastrobin for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children) and Females 13-49 years of age	None: There is no indication of an adverse effect attributable to a single dose. An aRfD was not established		
Chronic dietary (All populations)	NOAEL= 1.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day cPAD = 0.015 mg/kg/day	Chronic toxicity dog LOAEL = M/F 8.1/7.7 mg/kg/day based on body weight reductions and hepatocytomegaly and cytoplasmic changes associated with increased serum liver alkaline phosphatase indicative of cholestasis
Incidental oral short-term (1 to 30 days) and Intermediate-term (1-6 months)	NOAEL= 3.0 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males)
Dermal short-term (1 to 30 days)	None: There were no systemic or dermal toxicity findings in a 28-day dermal toxicity study in the rat up to the limit dose (1,000 mg/kg/day) and there were no developmental or neurotoxicity concerns raised in other studies		

Dermal intermediate-term (1 to 6 months)	NOAEL= 3.0 mg/kg/day dermal absorption factor = 2.3%	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Inhalation ^b Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 3.0 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90-day subchronic dog LOAEL = M/F 24.8/24.2 mg/kg/day based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver (cholestasis) in both sexes, and kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males)
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans"		

a "Point of Departure (POD)= A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures."
NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

b Toxicity by the oral route is assumed to be equivalent to the inhalation route. A subchronic inhalation toxicity study is not required for fluoxastrobin at this time. Although no subchronic inhalation data is available EPA has waived the data requirement. In determining the need for a subchronic inhalation study, EPA's weight of evidence decision process included both hazard and exposure considerations as well as incorporation of a presumed 10X Database Uncertainty Factor (UF_{db}) for the lack of this study. Specifically, with regard to exposure considerations, the Agency's Level of Concern in the evaluating the need for the subchronic inhalation study is a Margin of

Exposure (MOE) of 1,000 for inhalation exposure, which includes the 10X inter-species extrapolation factor, 10X intra-species variation factor, and the 10X UFdb. For fluoxystrobin, residential inhalation exposures resulted in MOEs higher than the LOC of 1,000 when using an oral Point of Departure (POD). This indicates that the lack of an inhalation study does not reduce the overall confidence in the risk assessment or result in an uncertainty (i.e., the study will not provide a POD sufficiently low to result in a risk of concern). Because EPA's decision to waive the subchronic inhalation study essentially incorporates an additional 10X UFdb (i.e. the study was only waived because risks were at least 10X lower than required by use of the inter- and intraspecies safety factors), a second additional 10X FQPA safety factor is not being retained for the protection of infants and children due to the absence of this study.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluoxastrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing fluoxastrobin tolerances in 40 CFR 180.609. EPA assessed dietary exposures from fluoxastrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fluoxastrobin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* A slightly refined chronic dietary exposure assessment was performed for fluoxastrobin using tolerance-level residues, average field trial residues, and 100 percent crop treated (PCT). This risk assessment was conducted using the DEEM-FCID Version 3.16. This model uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fluoxastrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluoxastrobin. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluoxastrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluoxastrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>. In addition to evaluating the EDWCs from the proposed uses, EDWCs were reevaluated for all existing uses with Pesticide Root Zone Model Ground Water (PRZM-GW), which models continued use of fluoxastrobin over many years. For the chronic dietary assessment, the most conservative EDWC (137 µg/L) was based on an existing turf use modeled with a 100 year simulation of 100 years of repeated applications, using the highest single maximum application rate and the highest yearly application rate.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluoxastrobin is currently registered for the following uses that could result in residential exposures: Spot treatment and/or broadcast control of diseases on turf, including lawns and golf courses. EPA assessed residential exposure using the following assumptions: Residential handler exposure for adults is expected to be short-term only. Intermediate-term and chronic exposures are not likely because of the intermittent nature of applications by homeowners. Since there are no toxicity findings for the short-term dermal route of exposure up to the limit dose, the residential handler assessment only includes the inhalation route of exposure. There is also potential for homeowners and their families (of varying ages) to be exposed as a result of entering areas that have previously been treated with fluoxastrobin. Exposure might occur on areas such as lawns used by children or recreational areas such as golf courses used by adults and youths. Potential routes of exposure include dermal (adults and children) and incidental oral ingestion (children). Since no acute hazard has been identified, an assessment of episodic granular ingestion was not conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found fluoxastrobin to share a common mechanism of toxicity with any other substances, and fluoxastrobin does not appear to produce a toxic metabolite

produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluoxastrobin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The available studies used to evaluate pre- and postnatal exposure susceptibility do not indicate increased susceptibility of rats or rabbits to fluoxastrobin. These studies include the following:

- i. Developmental toxicity studies in rats.
- ii. Developmental toxicity studies in rabbits.
- iii. A 2-generation reproduction study in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluoxastrobin is complete. EPA waived the requirement for a subchronic inhalation data based on, among other things, its conclusion that even if an additional 10X safety factor was applied, inhalation exposure would not raise a risk of concern.

ii. There is no indication that fluoxastrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluoxastrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. The rat developmental study was tested up to the limit dose (1,000 mg/kg/day), and the rabbit developmental study was tested up to 400 mg/kg/day (highest dose tested). At the highest dose tested, there were decreases in food consumption and body weight in the maternal animals, but there were no developmental effects. Furthermore, in the rat reproduction study, there was no sensitivity in the offspring of the pups relative to the parental animals.

iv. The exposure databases are estimated based on data that reasonably account for potential exposures. The chronic dietary food exposure assessment was conservatively based on 100 PCT assumptions, tolerance-level residues, and conservative ground and surface drinking water modeling estimates. New 2012 Residential Standard Operating Procedures (SOPs) were used to assess post-application exposure to children including incidental oral exposure. The residential post-application assessment assumes maximum application rates and conservative day zero hand-to-mouth activities. Although EPA has required additional data on transferable residues from treated turf for

fluoxastrobin, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (e.g., assuming residues do not degrade over the thirty day assessment period and assuming high-end activities on turf for every day of the assessment period). All of the exposure estimates for fluoxastrobin are based on conservative high-end assumptions and are not likely to result in underestimated risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluoxastrobin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluoxastrobin from food and water will utilize 30% of the cPAD for the general population, and 66% of the cPAD for all infants <1 year old, the population subgroup with the highest estimated chronic dietary exposure to fluoxastrobin. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluoxastrobin is not expected.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fluoxastrobin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluoxastrobin. Because all short- and intermediate-term quantitative hazard assessments (via the dermal and incidental oral routes) for fluoxastrobin are based on the same endpoint, a screening-level, conservative aggregate risk assessment was conducted that combined the short-term incidental oral and intermediate-term exposure estimates (i.e., the highest exposure estimates) in the risk assessments for adults. The Agency believes that most residential exposure will be short-term, based on the use pattern.

There is potential short- and intermediate-term exposure to fluoxastrobin via the dietary (which is considered background exposure) and residential (which is considered primary) pathways. For adults, these pathways lead to exposure via the oral (background), and dermal and inhalation (primary) routes. For children, these pathways lead to exposure via the oral (background), and incidental oral and dermal (primary) routes.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 610 for adults and 170 for children (1-2 years old). Because EPA's level of concern for fluoxastrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluoxastrobin is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluoxastrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry) is available to enforce the tolerance expression. Method No. 00604 is available for plant commodities and Method No. 00691 is available for animal commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs established for fluoxastrobin. However, there are Canadian MRLs established on sorghum and milk at 0.02 ppm, milk fat at 0.15 ppm, wheat bran at 0.15 ppm, and wheat grain at 0.1 ppm. Furthermore, the Canadian tolerance expression is not harmonized with the US tolerance expression. For plants and livestock, the Canadian tolerance expression does not include the Z-isomer.

C. Response to Comments

Two comments were received to the docket from members of the public. Both comments were the same. The commenters objected to the proposed tolerance on the ground that it would result in fluoride being added to treated crops. The commenters offered no basis for this claim.

The Agency reviewed all plant, livestock, and environmental degradation data and determined that the fluorine will not be released into the environment when applied to crops or non-agricultural areas. Neither free fluorine nor de-fluorinated fluoxastrobin was observed in food or water in any of the metabolism, degradation, and magnitude of residue studies.

V. Conclusion

Therefore, tolerances are established for residues of fluoxastrobin, in or on wheat, grain at 0.15 ppm; and tolerances are revised for milk and milk, fat at 0.03 ppm and 0.75 ppm respectively. Additionally, the established tolerance for wheat bran at 0.15 ppm is no longer needed and should be revoked because the recommended tolerance of 0.15 ppm for wheat, grain will cover expected residues in wheat bran.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 28, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.609:

- a. Remove “Wheat, bran” from the table in paragraph (a)(1).
- b. Add “Wheat, grain” in alphabetical order to the table in paragraph (a)(1).
- c. Revise “Milk” and “Milk, fat” in the table in paragraph (a)(2).

The amendments read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * *	* * *
Wheat, grain	0.15
* * *	* * *

(2) * * *

Commodity	Parts per million
* * *	* * *
Milk	0.03
Milk, fat	0.75
* * *	* * *

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